EXHIBIT A

# CORRECTIVE ACTION PLAN
## FOR
## ALLEN J. TOWER, SR. AND NUMED, INC.

## I. PREAMBLE

NuMED, Inc. and Allen J. Tower, Sr. hereby enter into this Corrective Action Plan ("CAP") to promote compliance by their officers, employees, and agents (collectively "NuMED"), with all Food and Drug Administration ("FDA") statutes, regulations, policies and procedures, including, but not limited to the Federal Food, Drug and Cosmetic Act, codified at 21 U.S.C. § 301, et. seq. Contemporaneously with this CAP, NuMED is entering into a Memorandum of Plea Agreement with the United States, and this CAP is incorporated by reference into the Memorandum of Plea Agreement.

## II. TERM AND SCOPE OF THE CAP

The period of the compliance obligations assumed by NuMED and Allen J. Tower, Sr. under this CAP shall be 5 years from the effective date of this CAP which is the date on which this CAP is executed. Each one-year period, beginning with the one-year period following the effective date, shall be referred to as a "Reporting Period."

For purposes of this CAP, "Covered Persons" includes all officers, employees, and agents of NuMED located in the United States whose job responsibilities relate to: (1) management and/or regulatory affairs; (2) quality assurance; and (3) device design, development, and/or manufacturing.

## III. CORPORATE INTEGRITY OBLIGATIONS

NuMED and Allen J. Tower, Sr. hereby agree to maintain a Compliance Program that includes the following elements:

### A. Retention of Independent Review Organization

NuMED shall retain an entity (or entities), such as an auditing or consulting firm (hereinafter "IRO") and such IRO will conduct an annual quality systems audit of NuMED. The annual quality systems audit will cover all matters regulated by the FDA, including, but not limited to the following: (1) complaint handling; (2) returned product handling; (3) design and labeling changes; and (4) process decision making as it relates to applications filed with the FDA. NuMED shall engage the IRO within 30 days of the effective date of this CAP, and the first audit will be conducted within 120 days of the effective date of this CAP.

For each year of the CAP, a complete copy of the IRO's annual audit shall be included in NuMED's Annual Reports to the FDA. The IRO and NuMED shall retain and make available to

the FDA upon request all work papers, supporting documentation, correspondence, and draft reports (those that are exchanged between the IRO and NuMED) relating to the engagements.

**B. Compliance Officer**

NuMED shall employ a Compliance Officer and shall continue to employ an individual to serve as its Compliance Officer during the term of this CAP. The Compliance Officer shall be responsible for overseeing the development of and coordinating the implementation of policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CAP and with all FDA statutes, regulations, policies and procedures. The Compliance Officer shall be responsible for overseeing NuMED's training and education program, and for monitoring the day-to-day compliance activities engaged in by NuMED as well as for any reporting obligations created under this CAP.

**C. Development and Dissemination of Regulatory Compliance Manual**

All current Covered Persons will be required to read the NuMED regulatory compliance manual which must be developed within 120 days of this CAP's effective date, and the manual must be read by newly hired Covered Persons within 10 days of hiring. The IRO must review the manual prior to its initial dissemination. A copy of the manual must be kept at each NuMED facility.

The manual should cover relevant FDA statutes, regulations, policies and procedures, including, but not limited to regulations concerning introducing or causing the introduction into interstate commerce of any "device" as that term is defined in 21 U.S.C. § 321(h). The manual shall specifically focus on the following: (1) the importance of accuracy, timeliness and honesty in reporting to regulatory agencies, emphasizing agency notification in case of adverse events; (2) the retention of data from health care providers to whom NuMED devices have been distributed; (3) dealings with regulatory inspectors and personnel; (4) the possible consequences to both NuMED and Covered Persons of failure to comply with all FDA statutes, regulations, policies and procedures; and (5) the requirement that all of NuMED's Covered Persons shall be expected to report to the Compliance Officer suspected violations of any FDA statutes, regulations, policies and procedures.

NuMED shall annually review the regulatory compliance manual with the aid of the IRO to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised regulatory compliance manual shall be distributed within 30 days after finalizing such changes.

**D. Disclosure Program**

Within 120 days of the effective date of this CAP, NuMED and Allen J. Tower, Sr. will certify to the FDA that there is a system in place which requires NuMED employees to report noncompliance with FDA statutes, regulations, policies and procedures to the Compliance Officer without retribution, and NuMED shall maintain its disclosure program during the term of this CAP. This certification shall be in the form attached as Exhibit A hereto.

For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, NuMED shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to the FDA, upon request.

**E. Training and Education**

Within 120 days after the effective date of this CAP, NuMED shall provide at least two hours of training to each Covered Person. This training, at a minimum, shall review NuMED's CAP requirements and all applicable FDA statutes, regulations, policies and procedures (including the sanctions for violations) relating to the development, distribution and sale of medical devices and all matters discussed in NuMED's regulatory compliance manual. All new Covered Persons must received this training within 60 days of hire.

The training and education required under this CAP should be provided by outside consultant trainers selected by NuMED with FDA approval. NuMED shall annually review the training, and, where appropriate, update the training to reflect changes in FDA statutes, regulations, policies and procedures, any issues discovered during internal and/or external audits and/or inspections, or any other relevant information.

After receiving the initial training described above, each Covered Person shall annually receive at least two hours of training on the topics outlined above. Each individual who is required to attend training shall certify that he or she has received the required training. The certification shall specify the Covered Person's position, the type of training received and the date received. The Compliance Officer shall retain the certifications, along with all course materials. These shall be made available to the FDA upon request.

## IV. IMPLEMENTATION AND ANNUAL REPORTS

### A. Implementation Report

Within 150 days of the effective date of this CAP, NuMED shall submit a written report to the FDA summarizing the status of its implementation of the requirements of this CAP. This Implementation Report shall include:

1. the name, address, phone number, and position description of the Compliance Officer required by section III.B., and summary of other non-compliance job responsibilities the Compliance Officer may have;

2. a copy of NuMED's regulatory compliance manual required by section III.C. and a certification that the manual has been reviewed by all Covered Persons;

3. a description of the disclosure program required by section III.D.;

4. to the extent not already provided, a copy of all training materials used for the training required by section III.E., a description of such training programs including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, and schedule of when the training sessions were held, and a certification that all Covered Persons have completed the applicable training and executed the certification(s) required by section III.E;

5. a summary and copies of the notifications that have occurred to all physicians, other medical personnel, and health care facilities that have implanted the CP Stent, and to all patients in whom the CP Stent has been implanted and a summary of any and all responses to such notifications that includes any questions and/or concerns raised by the recipients; and

6. documentation identifying the IRO, a copy of the contract between NuMED and the IRO which details the scope of the audit to be performed and a schedule of interim and final deadlines for the first annual audit.

### B. Annual Reports

NuMED shall submit to the FDA Annual Reports with respect to the status of, and findings regarding, NuMED's compliance activities for each of the five Reporting Periods. Each Annual Report shall include:

1. as described in section III.B, any change in the identity, position description, or other non-compliance job responsibilities of the Compliance Officer;

2. a summary of any significant changes or amendments to the regulatory compliance manual required by section III.C and the reasons for such changes (e.g., change in law);

3. a summary of the disclosures in the disclosure log required by section III.D.;

4. a copy of all training materials used for the training required by section III.E. (to the extent it has not already been provided), a description of such training conducted during the Reporting Period, including a list of targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. NuMED's response and corrective action plan(s) related to any issues raised by the IRO(s) audits; and

6. a revised summary/description of all engagements between NuMED and the IRO, as described in Section IV.A.6., if different than what was submitted as part of the Implementation Report.

The first Annual Report shall be submitted to the FDA no later than 90 days after the end of the first Reporting Period. Each subsequent Annual Report shall be submitted to the FDA no later than 90 days after the end of each subsequent Reporting Period.

**C. Certifications**

The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) to the best of his or her knowledge, except as otherwise described in the applicable report, NuMED is in compliance with all of the requirements of this CAP; and (2) the Compliance Officer has reviewed the report and has made reasonable inquiry regarding its content and believes that the information therein is accurate and truthful.

## V. FDA INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights the FDA may have by statute, regulation, or contract, the FDA or its duly authorized representative(s) may examine or request copies of NuMED's books, records, and other documents and supporting materials (to the extent such items are not protected under appropriately asserted legal privilege) and/or conduct on-site reviews of NuMED for the

purpose of verifying and evaluating: (a) NuMED's compliance with the terms of this CAP; and (b) NuMED's compliance with the applicable requirements of the FDA laws, policies and procedures. The documentation described above shall be made available by NuMED to the FDA or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction.

## VI. OBLIGATIONS REGARDING CP STENTS - BARE AND COVERED

NuMED and Allen J. Tower, Sr. shall provide full cooperation and assistance in the aorta coarctation clinical trial of the CP Stent - Bare and Covered - sponsored by Dr. Richard Ringel of The Johns Hopkins University School of Medicine. As part of that cooperation and assistance, NuMED and Allen J. Tower, Sr. shall provide to Dr. Richard Ringel the CP Stents - Bare and Covered - and the BIB Catheters required for the aorta coarctation clinical trial of the CP Stent free of charge. In addition, if the FDA approves and/or clears the CP Stent for distribution in the United States, NuMED and Allen J. Tower, Sr. shall, for the first five years following FDA approval of the CP Stent, provide the CP Stent at no cost to health care providers in the United States for treatment of coarctation of the aorta in accordance with the CP Stent's approved labeling.

## VII. NOTIFICATIONS AND SUBMISSIONS OF REPORTS

Unless otherwise stated in writing after the effective date of this CAP, all notifications, reports and approvals required under this CAP shall be submitted to Edward W. Thomas, FDA NY-DO, HFR-NE340, 300 Pearl Street, Suite 100, Buffalo, NY 14202.

## VIII. EFFECTIVE AND BINDING AGREEMENT

NuMED and Allen J. Tower, Sr. agree as follows:

A. This CAP shall be binding on the successors, assigns, and transferees of NuMED;

B. This CAP shall become final and binding on the date the final signature is obtained on the CAP; and

C. The undersigned NuMED signatory represents and warrants that he is authorized to execute this CAP.

**ON BEHALF OF NUMED, INC. AND ALLEN J. TOWER, SR.**

7/30/07

Allen J. Tower, Sr.
President
NuMED, Inc.
On behalf of himself and NuMED, Inc.

DATE

7/30/07

James Bessette
Kathleen Jennings
Counsel for Allen J. Tower, Sr. and NuMED, Inc.

DATE

**EXHIBIT A**

**CERTIFICATION OF IMPLEMENTATION OF DISCLOSURE PROGRAM**

I, Allen J. Tower, Sr., on my own behalf and on behalf of NuMED, Inc. ("NuMED"), hereby certify that NuMED has implemented a disclosure program which requires NuMED employees to report noncompliance with FDA statutes, regulations, policies and procedures to the Compliance Officer, [insert name], and NuMED will maintain this disclosure program during the term of the Corrective Action Program executed on [insert date]. I further certify that no adverse action or retribution will be taken against any NuMED employee for reporting suspected noncompliance with FDA statutes, regulations, policies and/or procedures.

Allen J. Tower, Sr.
President
NuMED, Inc.

7/30/07
DATE

Corporate Acknowledgment of Plea Agreement

By Unanimous Written Consent of the Board of Directors of NuMED, Inc., a copy of which is attached, the Board of Directors has authorized Allen J. Tower to execute the Memorandum of Plea Agreement on behalf of NuMED, Inc.

Dated: July 18th, 2007

Allen J. Tower
President
NuMED, Inc.

Dated: July 20th, 2007

James P. Bessette
Attorney for Defendant

Dated:

Kathleen M. Jennings
Attorney for Defendant

**UNANIMOUS WRITTEN CONSENT**
**OF THE BOARD OF DIRECTORS OF**
**NUMED, INC.**

**Pursuant to Section 708 of the Business Corporation Law**

We, the undersigned, being the directors of NuMED, Inc. (the "Corporation"), by affixing our signatures hereto, do hereby consent to and take the following action and adopt unanimously the following resolutions pursuant to the applicable provisions of the laws of the State of New York, as if the same were adopted at a meeting of the directors duly called and held:

RESOLVED, that after consulting with legal counsel in connection with a criminal action pending in the United States District Court for the District of Delaware, and due deliberation having been had thereon, and the directors believing it is in the best interest of the Corporation, the Corporation is hereby authorized to plead guilty to an information charging it with two misdemeanor counts of introducing and delivering into interstate commerce medical devices in violation of Title 21, Untied States Code, Section 331(a); and it is further

RESOLVED, that the President of the Corporation, Allen J. Tower, is hereby authorized and directed in the name of an on behalf of the Corporation to execute and deliver all such statements, certificates, agreements, instruments and other documents, including, but not limited to, the Memorandum of Plea Agreement and the Corrective Action Plan, and to take any and all other such actions as Allen J. Tower may consider necessary and appropriate in order to carry out and effectuate the foregoing resolutions and the guilty plea contemplated thereby

Dated: July 18th, 2007

Allen J. Tower, Sr., Director

Allen J. Tower, Jr., Director

Doug Villnave, Director